



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/656,653 | 09/03/2003 | Daniel J. Cook | 14/1454US | 8300 |

22822 7590 02/13/2009

LEWIS, RICE & FINGERSH, LC

ATTN: BOX IP DEPT.

500 NORTH BROADWAY

SUITE 2000

ST LOUIS, MO 63102

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

02/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDEPT@LEWISRICE.COM

KDAMMAN@LEWISRICE.COM

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/656,653 | | COOK, DANIEL J. | |
| | Examiner | | Art Unit | |
| | Darwin P. Erez | | 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-40, 43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) 6, 18, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-17, 20-27, 30-40, 43 and 45-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/08 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/20/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 7-17, 20-27, 30-33, and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 3773

Independent claims 1, 27, 30-33, 45 and 46 have been amended in an attempt to overcome the 35 USC 112, first rejection set forth in the Office action mailed on 8/19/08. However, the amendments to the claims are insufficient to overcome said rejection because the claims still recite "the distal lumen (of the distal end of the respiratory tube) passing through the peripheral portion of the positioning shield". As cited in the previous Office action, support is only provided for the distal end (including the distal lumen) of the respiratory tube passing through the rear portion of the positioning shield (page 13, lines 4-5). Furthermore, Fig. 2 of the application clearly shows that the distal end of the respiratory tube will pass through the rear portion, which is located between the pliable, posterior base 42 and the hollow, inflatable peripheral portion 40.

When treating the claims on the merit, the examiner will interpret the distal lumen of the distal end of the respiratory tube passing through the peripheral portion of the positioning shield.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 8-14, 17, 20, 25, 26, 33, 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,355,879 to Brain.

(claim 1) Brain discloses a laryngeal mask comprising:

Art Unit: 3773

an inflatable positioning shield, the shield having an inflatable peripheral portion 18, a pliable base 13 (constructed from silicone; col. 2, lines 59-60), a shield recess (defined by element 31), a rear portion 30 formed between the pliable base and the peripheral portion (where respiratory tube connects), wherein the posterior base has a recessed front portion (the tip portion); and

a respiratory tube 11 having a proximal end lumen, a curved tubular body (Fig. 1), a distal end passing through and secured to the rear portion of the positioning shield (Fig. 4), the distal end terminating at a distal lumen located within the rear portion, the distal lumen passing through and secured to the rear portion of the positioning shield such that tubes are capable of passing through the respiratory tube into the laryngeal opening (through aperture 14).

(claim 2) The respiratory tube and the position shield are pre-curved (Fig. 1).

(claim 8) The tubular body of the respiratory tube is of sufficient length to permit the proximal end to be displaced adjacent but external to the oral cavity (Fig. 1).

(claim 9) The proximal end lumen of the respiratory tube is adapted to attach to medical devices, such as a ventilator.

(claim 10) The peripheral portion of the inflatable positioning shields surrounds the laryngeal opening after inflation, which is the intended use of a laryngeal mask.

(claim 11) The inflatable positioning shield is generally ovoid in shape after inflation (Fig. 2).

(claim 12) The inflatable positioning is secured airtight to the exterior surface of the respiratory tube in socket 30.

Art Unit: 3773

(claim 13) The recessed front portion is in fluid communication with the respiratory tube. There is no structure to prevent the flow of air from the respiratory tube to the recessed front portion.

(claim 14) The positioning shield is of sufficient size to enclose the laryngeal opening.

(claim 17) The distal lumen defined in the socket 30 has the same cross-sectional shape as the respiratory tube.

(claim 20) The proximal end of the respiratory tube includes a tube adapter that provides a bigger diameter than the distal end of the respiratory tube.

(claim 25) The recessed front portion is part of the mask assembly that is made of silicone, so it is sufficiently pliable to cup the patient's trachea.

(claim 26) The peripheral portion is wedge-shaped (Fig. 2A).

(claims 33 and 35) See the rejection to claim 1.

(claim 37) The respiratory tube has a circular cross-sectional shape.

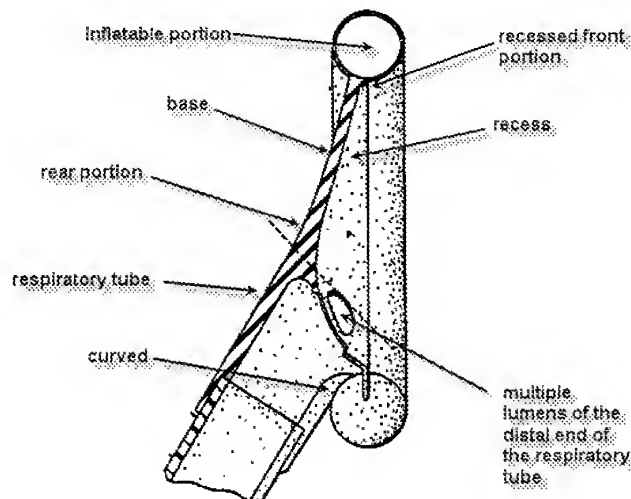
7. Claims 1, 2, 7-14, 20-26, 30, 31, 33, 35, 37, 39, 40 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by US Re. 35,531 to Callaghan et al.

(claim 1) Callaghan discloses a laryngeal mask comprising:

an inflatable positioning shield, the shield having an inflatable peripheral portion, a pliable base, a shield recess, a rear portion formed between the pliable base and the peripheral portion (see figure below), wherein the positioning shield base has a recessed front portion (see Fig. 2, the front tip portion); and

Art Unit: 3773

a respiratory tube having a proximal end lumen, a curved tubular body, a distal end passing through and secured to the rear portion of the positioning shield, the distal end terminating at a distal lumen located within the rear portion, the distal lumen passing through and secured to the rear portion of the positioning shield such that tubes are capable of passing through the respiratory tube into the laryngeal opening (see figure below).



(claim 2) The respiratory tube and the position shield are pre-curved (see figure above).

(claim 7) The respiratory tube has multiple lumens 27, wherein one of the lumens is larger than the other lumens.

(claim 8) The tubular body of the respiratory tube is of sufficient length to permit the proximal end to be displaced adjacent but external to the oral cavity.

(claim 9) The proximal end lumen of the respiratory tube is adapted to attach to medical devices, such as a ventilator.

Art Unit: 3773

(claim 10) The peripheral portion of the inflatable positioning shields surrounds the laryngeal opening after inflation, which is the intended use of a laryngeal mask.

(claim 11) The inflatable positioning shield is generally ovoid in shape after inflation.

(claim 12) The inflatable positioning is secured airtight to the exterior surface of the respiratory tube.

(claim 13) The recessed front portion is in fluid communication with the respiratory tube. There is no structure to prevent the flow of air from the respiratory tube to the recessed front portion.

(claim 14) The positioning shield is of sufficient size to enclose the laryngeal opening.

(claim 20) The distal lumens 27 has a smaller diameter than the proximal end of the respiratory tube.

(claims 21, 23 and 24) The distal lumen comprises multiple lumens, where one can be viewed as an upper portion and another can have a lower portion (depends on the orientation of the device), and wherein the lumens have different diameters.

(claim 22) The distal lumen is an opening, so it is inherently open upon assertion of pressure.

(claim 25) The recessed front portion is part of the mask assembly and is sufficiently pliable to cup the patient's trachea.

(claim 26) The peripheral portion is wedge-shaped.

(claim 30) See the rejections to claims 1 and 23.

Art Unit: 3773

(claim 31) See the rejections to claims 1 and 7.

(claims 33 and 35) See the rejection to claim 1.

(claim 37) The respiratory tube has a circular cross-sectional shape.

(claim 39) See the rejections to claims 1 and 7.

(claim 40) The multiple lumens 27 of Callaghan provides an alternative means for ventilation when one of said lumens is blocked. This is an equivalent to the means disclosed by the applicant.

(claims 46-48) See the rejections to claims 1 and 7.

8. Claims 34 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,240,922 to Pagan.

Pagan teaches a laryngeal mask comprising horizontal runners 31-33 or the deflector shown in Fig. 6, which is viewed as a means for elevating an epiglottis and surrounds a portion of the perimeter of the lumen and does not obstruct the lumen (the lumen is not obstructed/closed). It is also noted that the Pagan reference qualifies as a prior art because the structure of the horizontal rib is not present in any of the parent cases.

It is further noted that the means plus function limitation in claim 34 does not properly invoke 35 USC 112, sixth paragraph because the means is modified by sufficient structure (surrounding a portion of the perimeter of the lumen formed by the distal end of the respiratory tube) for achieving the specified function.

Art Unit: 3773

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3-5, 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US 5,682,880 to Brain ('880).

The '879 reference is silent with regards to the respiratory tube having an elliptical (oval) cross-section and made from a material with a low coefficient of friction to facilitate the delivery of an endotracheal tube. However, the use of a respiratory tube having an elliptical cross-section in a laryngeal mask is well known in the art. For instance, the '880 reference discloses a respiratory tube having an elliptical cross-section with an endotracheal tube located within (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respiratory tube of the '879 reference to that of the '880 reference because it allows an elliptical endotracheal tube to be used and inserted into the respiratory tube and

Art Unit: 3773

laryngeal mask with little difficulty. The '880 reference also teaches that the respiratory tube is made of silicone, which has a low coefficient of friction. The respiratory is also flexible (col. 2, line 67) and is therefore capable of deforming radially.

12. Claims 3-5, 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al., as applied to the rejections above, and in view of US 5,682,880 to Brain ('880).

Callaghan is silent with regards to the respiratory tube having an elliptical (oval) cross-section and made from a material with a low coefficient of friction to facilitate the delivery of an endotracheal tube. However, the use of a respiratory tube having an elliptical cross-section in a laryngeal mask is well known in the art. For instance, the Brain ('880) discloses a respiratory tube having an elliptical cross-section with an endotracheal tube located within (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respiratory tube of Callaghan to that of Brain ('880) because it allows an elliptical endotracheal tube to be used and inserted into the respiratory tube and laryngeal mask with little difficulty. Brain ('880) also teaches that the respiratory tube is made of silicone, which has a low coefficient of friction. The respiratory is also flexible (col. 2, line 67) and is therefore capable of deforming radially.

13. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US 6,240,922 to Pagan.

(claims 15 and 16) Brain teaches all the limitations of the claims except for the recessed front comprising at least one support member adapted to stabilize the pliable

Art Unit: 3773

base, wherein the at least one support member is at least one raised horizontal runner.

However, Pagan teaches a similar laryngeal mask, wherein the mask includes a recessed front portion with horizontal runners **31-33**, which act to hold the epiglottis away from the tube opening. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mask of Brain to include the ribs taught by Pagan because it would prevent the epiglottis from blocking the tube opening during insertion of the mask assembly. The modification to include the ribs would also inherently stabilize the pliable base.

14. Claims 15, 16, 32, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al., and in view of US 6,240,922 to Pagan.

Callaghan discloses all the limitations of the claims except for the recessed front comprising at least one support member adapted to stabilize the pliable base, wherein the at least one support member is at least one raised horizontal runner. However, Pagan teaches a similar laryngeal mask, wherein the mask includes a recessed front portion with horizontal runners **31-33**, which act to hold the epiglottis away from the tube opening. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mask of Callaghan to include the ribs taught by Pagan because it would prevent the epiglottis from blocking the tube opening during insertion of the mask assembly. The modification to include the ribs would also inherently stabilize the pliable base.

15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain ('879) in view of US 4,995,388 to Brain ('388).

The '879 reference teaches all the limitation of the claim, including a flexible respiratory tube, but is silent with regards to the materials used for the respiratory tube. However, the '388 reference teaches a similar laryngeal mask that uses a silicone based respiratory tube (col. 4, lines 28-29). Therefore, because these two flexible tubes were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible silicone rubber tube for the flexible tube of the '879 reference.

16. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al. in view of US 4,995,388 to Brain ('388).

Callaghan teaches all the limitation of the claim, including a flexible respiratory tube, but is silent with regards to the materials used for the respiratory tube. However, the '388 reference teaches a similar laryngeal mask that uses a silicone based respiratory tube (col. 4, lines 28-29). Therefore, because these two flexible tubes were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible silicone rubber tube for the flexible tube of Callaghan.

17. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0051734 to Brain.

Brain discloses a laryngeal mask having a distal end having two portions (see Fig. 5). Brain is silent with regards to one of the portions being larger than the other portion. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of Brain to have one of the

Art Unit: 3773

portions be larger than the other since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It is also noted that this Brain reference qualifies as a prior art because the keyhole structure is not present in any of the parent cases.

Response to Arguments

18. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773